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(21) International Application Number: PCT/AU99/00609 (22) International Filing Date: 29 July 1999 (29.07.99) (30) Priority Data: PP 5386 21 August 1998 (21.08.98) AU PQ 0882 9 June 1999 (09.06.99) AU (71) Applicant (for all designated States except US): ADVANCED NUTRITIONAL FOODS PTY. LIMITED [AU/AU]; 7 Pearl Bay Avenue, Mosman, NSW 2088 (AU). (72) Inventor; and (75) Inventor/Applicant (for US only): STRONG, Maxwell, John [AU/AU]; 7 Pearl Bay Avenue, Mosman, NSW 2088 (AU). (74) Agent: GRIFFITH HACK; G.P.O. Box 4164, Sydney, NSW 2001 (AU).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: COMPOSITION (57) Abstract A composition comprising a calcium source and an amount of oligosaccharide effective to solubilise the calcium when the composition is prepared as a food product or is added to a food or beverage.		

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COMPOSITION**Technical Field**

The present invention relates to a composition comprising oligosaccharide and calcium. The composition is
5 suitable to be prepared as a food product or for the addition of calcium and milk minerals into a range of foods and beverages.

Background Art

One of the major diseases facing us today is
10 osteoporosis. Every year osteoporosis costs Australians over eight hundred million dollars in health care. This figure is set to increase as the population grows older, unless effective prevention takes place. Once thought of as part of the ageing process, osteoporosis has now become
15 one of Australia's biggest health problems.

Osteoporosis is the disease which is characterised by demineralisation of the bones. As calcium is lost, the bones become thin and brittle, creating what is known as the 'honeycomb' effect. As a result, the bones are more
20 susceptible to fractures, even when carrying out everyday activities such as lifting and bending. In Australia, osteoporosis is the cause of over 15,000 hip fractures, 24,000 forearm fractures and over 10,000 arm fractures each year. The Dubbo Osteoporosis Epidemiology Study which took
25 place between 1989 and 1992 found that over the age of 60, almost 60 per cent of women and 30 per cent of men suffered from at least one fracture due to osteoporosis.

While it is largely a preventable condition, osteoporosis affects almost one half of Australian women
30 and one third of Australian men. After about the age of 35, the body automatically begins to use up its calcium stores and for this reason, osteoporosis is most common in older people. However, it can also affect younger people, especially those whose hormonal balance has been
35 compromised by illness, eating disorders or over-exercise.

Building up calcium levels before this time is especially important for prevention of this disease.

As the most effective way to build strong, healthy bones, an adequate and regular intake of calcium needs to be maintained from early childhood right through to old age. The more calcium stored in the bones, the less risk of osteoporosis later in life. Poor storage of calcium in the bones means a greater risk of fractures due to osteoporosis. While the rate of bone depletion in women and men is similar before menopause, post menopausal women lose bone density at a much faster rate than men of the same age. This is because the female sex hormone oestrogen plays a major part in the maintenance of bone calcium balance. It is also thought that the decrease in testosterone in older men can also contribute to an increased risk of osteoporosis.

Our best dietary source of calcium is dairy products such as milk, yogurt, cheese, etc and generally three servings of these dairy products each day is able to provide an adequate intake of calcium. In reality however, less than one-half of the population actually consume three servings of dairy products each day and women of all age groups when questioned as to why they do not drink milk answer that they consider it to be fattening. Others do not like the taste, while some believe it to be mucous-forming. In addition, our population is increasingly becoming more multi-racial, with many coming from those countries which do not have a tradition of dairy products in their diets. These people often have a lactose intolerance and do not consume dairy products for this reason. It is clear that the minerals found in dairy milk, particularly calcium, should be available in a form which would overcome the objections many people have in consuming three servings of milk or other dairy products on a regular basis.

Oligosaccharides have growth-enhancing effect on the beneficial bacteria, Lactobacilli and Bifidobacteria present in the human gastrointestinal tract, and belong to that group of foods known as prebiotics. As well as enhancing growth of the health promoting bacteria, oligosaccharides have the effect of reducing the numbers of harmful bacteria such as *Escherichia coli* and *Clostridia*. The lactobacilli and bifidobacteria are known to promote a number of important therapeutic and prophylactic effects, including stimulation of the host immune system.

Calcium in dairy products is found in combination with other important minerals, phosphorous and magnesium, and researchers in this area think that the combination of these minerals as well as their ratio, is an important factor in the enhanced absorbability of calcium. It would therefore be of considerable advantage in the addition of calcium to foods and beverages if the source of calcium used were to be the natural calcium from dairy products and, more particularly, if the calcium was in combination with all the minerals found in milk.

Disclosure of the Invention

The present invention provides a composition comprising a calcium source and an amount of oligosaccharide effective to solubilise the calcium when the composition is prepared as a food product or is added to a food or beverage.

Typically, the calcium source and oligosaccharide are present in a ratio of about 1-2 : about 2-1 by weight.

By 'a calcium source' we mean calcium in the form of a salt or calcium which is in the form of a mineral concentrate obtained from dairy milk or a mixture of both. Suitable calcium salts include carbonate, gluconate, lactate, phosphate, citrate, citrate malate, ascorbate, hydroxide, glycerophosphate, chloride, alginate or the like or a mixture of salts. Calcium which is in the form of a mineral concentrate obtained from dairy milk contains other

minerals such as potassium, magnesium, zinc, phosphorous, iron and manganese. A commercially available mineral concentrate of milk is a good calcium source and is also suitable for use in the present invention. One such product is ALAMINTM 996 which is a product of New Zealand Milk Products (Australia) Pty Limited. Another product which is known as DAIRYCAL is supplied by Cottee Dairy Products Pty Limited.

The oligosaccharide is any oligosaccharide, but is preferably fructo-oligosaccharide or isomalto-oligosaccharide. Commercially available preparations of oligosaccharide such as RAFTILOSE[®] supplied by Fernz Australia Limited, can also be used. RAFTILOSE[®] is a registered trade mark of Raffinerie Tirlemontoise En Neerlandais Tiense of Belgium.

The composition of the present invention can be prepared as a food product such as a chewy-textured confectionery product or can be used to supplement most foods and liquid beverages with calcium.

The advantage of the present invention is that the composition can be added to liquid beverages to provide up to 800mg of calcium in a single serving, ie 250mls, which is 100% of the Australian Recommended Dietary Intake (RDI) of calcium. The composition of the present invention can also be prepared as a chew using ordinary confectionery manufacturing techniques to provide a chew having up to 100% RDI of calcium. In the chew and in the liquid beverage, the calcium is completely solubilised and there is no gritty or powdery taste.

The composition of the present invention can also be added to foods while maintaining the calcium in a completely solubilised form.

Foods which can be supplemented with calcium using the composition of the present invention include powdered milk, sauces, dressings, soups, bread, biscuits, cereal, pasta, noodles, cakes, desserts including dairy desserts,

ice cream, frozen confections including dairy or soy, yoghurt, snacks such as muesli bars and the like.

Liquid beverages that can be supplemented with calcium using the composition of the present invention are water, soft drinks, health/energy drinks including those prepared for athletes and other water based beverages, all types of milk products, including fresh and UHT milk, equivalent yoghurt drinks and other cultured milk beverages, equivalent soy milk beverages, fruit drinks and fruit juices. When supplementing beverages such as water, soft drinks or flavoured drinks, a small amount of an acid such as ascorbic acid is added to counteract the alkalinity and to improve taste.

Foods and liquid beverages can be supplemented with calcium using the composition of the present invention without adversely affecting their flavour, texture or functionality.

The composition of the present invention can comprise additional ingredients that are commonly found in foods and beverages without adversely affecting the solubility properties of the composition. Such additional ingredients include modifying agents, thickeners, mineral salts, food acids, emulsifiers and humectants. Examples of these additional ingredients can be found in the Australian Food Standards Code. Other additional ingredients include vitamins, minerals such as iron and magnesium, colouring agents, flavouring agents and probiotic dried cultures (such as *E.faecium* PR88), probiotic live cultures, phytoestrogens, colostrum and other immune system enhancing agents.

We have found that when the soluble dietary fibre, oligosaccharide is combined with calcium, there is an unexpected and previously unknown increase in calcium solubility. A further advantage of the present invention is that calcium bioabsorption is increased significantly

when calcium is consumed together with the soluble dietary fibres such as oligosaccharides.

Accordingly, in another aspect the present invention provides a method of enhancing the solubility of calcium which comprises solubilising the calcium in the presence of oligosaccharide.

Mode(s) for Carrying out the Invention

The oligosaccharides used in the present invention are commercially available or can be readily prepared by methods known to those skilled in the art. Fructo-oligosaccharide can be extracted from Inulin by methods known to those skilled in the art. Inulin is the storage carbohydrate of about 30,000 plants. Isomalto-oligosaccharide is the hydrolysis product of starch.

Calcium salts and the mineral concentrate from milk are also commercially available. The preparation of a mineral concentrate from dairy milk or whey involves initial removal of the fat and most of the protein (casein) from the milk. The milk is then subjected to ultra filtration through micro-membranes which separates the larger whey protein molecules, leaving the smaller molecules of the mineral stream. Removal of the whey protein fraction leaves lactose, minerals and trace minerals. The lactose is removed using reverse osmosis techniques, finally leaving a mineral concentrate which is comprised principally of calcium, potassium, magnesium, zinc, phosphorous, iron and manganese. This concentrate is then dried forming a white, free-flowing and poorly soluble powder.

The composition of the present invention can be used to prepare a chewy-textured confection by using process equipment and techniques known to those skilled in the art of confectionary manufacture.

The composition of the present invention can be added to any milk product. The milk is thoroughly mixed using normal dairy mixing equipment. The milk product is then pasteurised and homogenised in the normal manner resulting

in a fortified milk with the required target level of calcium. When the composition is added to other beverages, normal commercial mixing equipment is used. When the composition is added to foods, it can be treated like an additional ingredient and treated like any other ingredient, and the foods are processed and prepared in the normal manner. For example, a dry mix of the calcium source and oligosaccharide can be added to the dry dough ingredients and the ingredients are processed in the usual manner for making the bread. Milk and other beverages prepared in this way produce high-calcium products in which there is virtually no settlement of calcium. Food products prepared by including the composition of the present invention have a high level of calcium in a solubilised form without adversely affecting their flavour, texture or functionality.

The skilled addressee would understand that when the composition of the present invention comprises ingredients in addition to the calcium source and oligosaccharide, the amount of these additional ingredients are dependent on which food or beverage is to be supplemented and the amount is, in most instances, determined by relevant regulatory and/or health authority rules and guidelines.

In the following examples 1, 3 and 5, the calcium is in the form of the commercially available milk mineral concentrate ALAMINTM 996 and in examples 1-5, the oligosaccharide is the commercially available RAFTILOSE[®] product.

Example 1

Whole Milk

Milk mineral concentrate	1.7gms
Oligosaccharide	1.0gm
Milk	made up to 250mls

The milk mineral concentrate and oligosaccharide are blended with 250mls of milk to produce a calcium level of

800mg per serving of 250mls of milk. This is 100% of the RDI of calcium.

Example 2

Whole Milk

- | | | |
|---|--|------|
| 5 | Calcium lactate/calcium gluconate
(1:2 molar ratio) | 2gms |
| | Oligosaccharide | 1gm |
| | Milk made up to 250mls | |

- 10 The milk is prepared as per Example 1 to provide
approximately 500mg of calcium per 250ml serving of milk.

Example 3

Apple Juice

- A dry mix is prepared containing 45% milk mineral concentrate and 55% oligosaccharide. The dry mix is blended with apple juice using 2.3gms per 200ml serving of apple juice to provide 290mg of calcium per 200ml of apple juice. This is approximately 36% of the RDI of calcium.

Example 4

- 20 Water

- A dry mix is prepared having 80% calcium lactate and 20% oligosaccharide. This is blended with water (5gm per litre) to provide 400mg of calcium in a litre of water. 45mg of ascorbic acid is added to improve taste. This provides 10% of the RDI of calcium in a 200ml serving of water.

Example 5

Bread

- A dry mix is prepared having 50% milk mineral concentrate and 50% oligosaccharide. This is added (20gms per loaf) to the dry dough and other ingredients which provides approximately 130mg of calcium per slice of bread.

The same dry mixed blend can be used to supplement biscuits, pasta and cereal with calcium.

Example 6

Confection

	Flavour	q.s.
	Oligosaccharide and calcium 1:1 mix	40.0%
5	milk solids	3.0%

made up to a chewy bar of approximately 6g using other ingredients such as fillers, gelatine and sugar that are usually used in the manufacture of confectionary.

In example 6, the calcium source is the DAIRYCAL product and the oligosaccharide is isomaltooligosaccharide..

The above ingredients are solubilised, mixed and prepared in appropriate shapes in process equipment known to those skilled in the art of confectionery manufacture.

The confection is a chewy-textured product of about 6gms, each confection having the calcium level equivalent to one glass of dairy milk (290mg) which is 36% of the RDI of calcium.

Example 7

Same as for example 6, except that the oligosaccharide is fructooligosaccharide.

Example 8

Orange juice

	phytoestrogen	1.5g
	DAIRYCAL	1.07g
25	RAFTILOSE	0.5g

made up to 250 mls with orange juice.

The phytoestrogen is ISOLIFE Micro. ISOLIFE is a trade mark of Schouten Products BV, Netherlands and the product is available from Soy Health Pty Ltd in New South Wales, Australia

Example 9

Water

A dry mix is prepared using calcium lactate and calcium gluconate in a 1:2 molar ratio. To 0.67 gms of this dry mix is added 0.7g of RAFTILOSE and .05g of ascorbic acid. This is blended with water to make up to

ascorbic acid. This is blended with water to make up to 250mls of water containing 74mg of calcium being 9% of RDI.

Example 10

Same as for example 9, except that 1.38g of the dry
5 mix is added with 0.13g of RAFTILOSE to 600ml of water.
This provides 150mg of calcium being 18% of RDI.

The skilled addressee would understand that calcium
is more soluble in some foods and beverages than in others.
Therefore, the amount of oligosaccharide required to
10 solubilise a given amount of calcium is to a certain extent
dependent upon which food or beverage is to be
supplemented.

In the claims that follow and in the summary of the
invention, except where the context requires otherwise due
15 to express language or necessary implication, the word
'comprising' is used in the sense of 'including', ie the
features specified may be associated with further features
in various embodiments of the invention.

CLAIMS

1. A composition comprising a calcium source and an amount of oligosaccharide effective to solubilise the calcium when the composition is prepared as a food product or is added to food or beverage.
2. A composition according to claim 1 wherein the calcium source and oligosaccharide are present in a ratio of about 1-2 : about 2-1 by weight.
3. A composition according to claim 1 or 2, wherein the calcium source is calcium which is in the form of a mineral concentrate obtained from dairy milk or a salt of calcium selected from carbonate, gluconate, lactate, phosphate, citrate, citrate malate, ascorbate, hydroxide, glycerophosphate, chloride, alginate or a mixture of salts and wherein the oligosaccharide is fructooligosaccharide or isomaltooligosaccharide.
4. A composition according to claim 1 or 2, wherein the source of calcium is a mineral concentrate obtained from dairy milk and the oligosaccharide is fructooligosaccharide.
5. A confectionery product comprising a composition according to any one of claims 1 to 4.
6. A food to which has been added a composition according to any one of claims 1 to 4.
7. A beverage to which has been added a composition according to any one of claims 1 to 4.
8. A method of enhancing the solubility of calcium which comprises solubilising the calcium in the presence of oligosaccharide.
9. A method according to claim 8, wherein the calcium is a calcium source and the calcium source and oligosaccharide are as defined in claim 3.
10. A method according to claim 9, wherein the calcium source and oligosaccharide are present in a ratio of about 1-2 : about 2-1 by weight.

INTERNATIONAL SEARCH REPORT

International application No.
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A. CLASSIFICATION OF SUBJECT MATTER																						
Int Cl ⁶ : A23G 3/00; A23D 13/00; A23C 9/152; A23L 2/52, 2/02, 2/00; A61K 31/715, 35/20, 33/06																						
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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) WPAT, Medline, Chemical Abstracts, FSTA. Search terms: oligo(sacc: poly(sacc: fructo(oligo: isomalto(oligo: fructooligo isomaltooligo polysacc: oligosacc: raftilose# calcium alamin dairycal milk iso(malto(oligosaccharid?																						
C. DOCUMENTS CONSIDERED TO BE RELEVANT																						
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																				
X	JP 07285872 A (KYODO NYUGYO KK) 31 October 1995	1-10																				
X	JP 07067575 A (SUNTORY LTD) 14 March 1995	1-10																				
X	JP 09037711 A (TOKUMARU SENNOSUKE) 10 February 1997	1-7																				
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input type="checkbox"/> See patent family annex																						
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INTERNATIONAL SEARCH REPORT

International application No.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP 63-24847 A (YOSHIROU SHINTOMAI) 2 February 1988	1-10
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X	The Journal of Nutrition, vol. 125, no. 9, 1995, Ohta et al., "Calcium and Magnesium Absorption from the Colon and Rectum Are Increased in Rats Fed Fructooligosaccharides", pages 2417-2424	1-10